

Message

From: Kerr, Julia [kerr.julia@epa.gov]
Sent: 3/6/2020 1:28:15 PM
To: MAUNE, ONA [AG/1005] [ona.maune@monsanto.com]
CC: Schmid, Emily [Schmid.Emily@epa.gov]; NYANGULU, JAMES M [AG/1920] [james.nyangulu@bayer.com]
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Ona,

I have started working on my label review for this action. However, I will need to review your resubmission to see which of my comments are still applicable. While I cannot estimate an exact date of completion, I have not forgotten this action, and I do expect to complete it soon.

Thank you for checking in,

Julia Kerr
Biologist
Herbicide Branch
Registration Division
Office of Pesticide Programs
(703) 347-0386

From: MAUNE, ONA [AG/1005] <ona.maune@monsanto.com>
Sent: Thursday, March 5, 2020 5:21 PM
To: Kerr, Julia <kerr.julia@epa.gov>
Cc: Schmid, Emily <Schmid.Emily@epa.gov>; NYANGULU, JAMES M [AG/1920] <james.nyangulu@bayer.com>
Subject: FW: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Julia,

I'm following up on this pending master label amendment, which is still our top non-PRIA priority action under Company No. 71995. We understand your team is still significantly understaffed, however we would appreciate any estimated timing. We're still trying to possibly implement these label changes in the retail market this year. Please reach out to me directly if you have any questions. Thanks in advance.

Kindest Regards, Ona

From: MAUNE, ONA [AG/1005]
Sent: Wednesday, February 19, 2020 3:43 PM
To: 'Kerr, Julia' <kerr.julia@epa.gov>
Cc: Schmid, Emily <Schmid.Emily@epa.gov>; NYANGULU, JAMES M [AG/1920] <james.nyangulu@bayer.com>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Good Afternoon Julia,

Thanks for the update. In order to incorporate the required label claim clarifying how glyphosate works per the Glyphosate Interim Registration Review Decision posted 1/30/2020, we've revised the master label to replace current

label claims with the following statement "Glyphosate works by targeting an enzyme that is essential for plant growth" (pg. 3 & 13). In addition, we've incorporated several minor changes and typo corrections. Both a clean copy (071995-00025-20200219.pdf) and a marked copy are attached.

Please feel free to reach out to me directly with any questions. As always, thanks in advance for your assistance.

Kindest Regards, Ona

From: Kerr, Julia <kerr.julia@epa.gov>
Sent: Tuesday, January 21, 2020 3:19 PM
To: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>
Cc: Schmid, Emily <Schmid.Emily@epa.gov>; NYANGULU, JAMES M [AG/1920] <james.nyangulu@bayer.com>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Ona,

Thank you for checking in. I am looking at your label amendment now, it will still need to go through the secondary review process once I am finished. I will keep you updated as we make progress.

I apologize for the delay, thank you for your continued patience.

Kind regards,

Julia Kerr
Biologist
Herbicide Branch
Registration Division
Office of Pesticide Programs
(703) 347-0386

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>
Sent: Tuesday, January 21, 2020 1:07 PM
To: Kerr, Julia <kerr.julia@epa.gov>
Cc: Schmid, Emily <Schmid.Emily@epa.gov>; james.m.nyangulu@monsanto.com
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Good Afternoon Julia,

I'm following up on this pending Master Label amendment for **EPA# 71995-25**. As mentioned previously this is our top non-PRIA fast track action under Company No. 71995. We understand you are still significantly backlogged, however this action has been pending for over 16-months. Appreciate if you could advise on estimated timing in your queue, as we're still trying to implement label changes potentially for mid-season 2020. As always, thanks in advance for your assistance.

Kindest Regards, Ona

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Friday, December 13, 2019 5:34 AM
To: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>; Kerr, Julia <kerr.julia@epa.gov>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Ona,

Since you need the ABN with this amendment, Julia can use this version of the label when she gets to it in her queue. She can give you a more specific idea of where this is in her queue but in my stack to assign, the oldest ones are from January 2018.

Thank you for your patience!

Best regards,
Emily

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>
Sent: Thursday, December 12, 2019 3:00 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>; Kerr, Julia <kerr.julia@epa.gov>
Cc: james.m.nyangulu@monsanto.com
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Good Afternoon Emily,
I'm following up on this pending Master Label amendment. We cannot implement the ABN without the this label amendment approval; thus the ABN 'Roundup® Super Concentrate Weed & Grass Killer' (just changing the location of 'Super Concentrate') can be consolidated within this action. I've included a highlighted Master Label revision reflecting the ABN listed on page 1; in addition to couple minor changes consistent with previous accepted labels, such as EPA# 71995-37. A clean copy is also attached: 071995-00025-20191212.pdf.

*Also, I wanted to highlight this pending EPA# 71995-25 Master Label amendment is significantly similar (more than 90% overlap) to another pending Master Label amendment for EPA# 71995-29 submitted on 8/22/2019 (CDX_2019_006852). These could potentially be reviewed concurrently to maximize efficiencies; as we're aware your team is still significantly backlogged. Both of these actions take priority over all our other pending non-PRIA actions under Company Number 71995.

Appreciate if you or Julia could provide estimated timing in the queue, as we're still trying to implement label changes for mid-season 2020. Thanks in advance for your assistance.

Kindest Regards, Ona

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Wednesday, August 7, 2019 9:36 AM
To: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>; Kerr, Julia <kerr.julia@epa.gov>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Ona,

We are encouraging registrants to consolidate their actions since we have an unmanageable amount of fast track amendment and notifications to process; however, in this case I would suggest sending the alternate brand name as a notification because we should be able to process that much faster.

Best regards,
Emily

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>
Sent: Tuesday, August 06, 2019 12:09 PM
To: Kerr, Julia <kerr.julia@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>
Cc: james.m.nyangulu@monsanto.com; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Julia and Emily,

Thanks for your prompt response. We truly do understand you're doing the best you can with the limited resources available. However, it's difficult for us to manage implementing product label updates due to the seasonal nature of our business and strict retailer deadlines. Please reach out if there is anything we can do to help expedite the review of this master label amendment. As mentioned, the majority of the proposed language & formatting revisions are consistent with the recent acceptance of EPA# 71995-37 dated 3/28/2019 (reviewed by Beth Benbow).

Also, we would like to request an Alternative Brand Name (ABN), Roundup® Super Concentrate Weed & Grass Killer (just changing the location of 'Super Concentrate'). Would you prefer this be submitted as a separate ABN Notification or be combined with this pending Amendment?

I will loop back with James from our DC Office, who has been managing overall Bayer priorities at an RD level.

Kindest Regards, Ona

From: Kerr, Julia <kerr.julia@epa.gov>
Sent: Monday, August 05, 2019 1:29 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>; MAUNE, ONA [AG/1005] <ona.maune@bayer.com>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Ona,

Unfortunately, due to the current backlog I cannot offer an accurate estimate of when this action may be completed. We are doing our best to complete non-PRIA actions whenever possible, but the current workload has made it increasingly difficult to keep up. I will let you know if there is any change in the status of this action.

I apologize for the delay and I thank you for your continued patience as we try to catch up with our backlog of actions.

Kind regards,

Julia Kerr
Biologist
Herbicide Branch
Registration Division
Office of Pesticide Programs
(703) 347-0386

From: Schmid, Emily
Sent: Monday, August 5, 2019 1:02 PM
To: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>
Cc: Kerr, Julia <kerr.julia@epa.gov>; james.m.nyangulu@monsanto.com; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Ona,

Julia can let you know where this is in her queue but as I previously explained, it is very unlikely that it is high enough in her queue that it will be done soon.

As far as I know, individual teams aren't taking requests for non-PRIA action priorities. These are being done divisionally and should be expressed to the immediate office.

Thank you for your patience. We hate that this is such an inconvenience and really are doing our best.

Best regards,
Emily

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>
Sent: Monday, August 05, 2019 12:21 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kerr, Julia <kerr.julia@epa.gov>; james.m.nyangulu@monsanto.com; Kenny, Daniel <Kenny.Dan@epa.gov>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Good Morning Emily,
I'm following up on this non-PRIA Amendment under EPA Company No. 71995 and would appreciate any feedback on the estimated review timing? It's my understanding James reached out to Dan Kenny (copied) to re-communicate this pending action as a top company priority. I understand your team is significantly understaffed and completely backlogged; however this pending action has reached critical timing on whether we can implement revised labels for 2020.

As mentioned, the revised master label for this residential concentrate product, including the majority of the proposed language & formatting, are consistent with the recent acceptance of EPA# 71995-37 dated 3/28/2019. I've included the submission information below and attached the cover memo for your reference.

Kindest Regards, Ona

From: MAUNE, ONA [AG/1005]
Sent: Monday, July 15, 2019 10:25 AM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: Kerr, Julia <kerr.julia@epa.gov>; NYANGULU, JAMES M [AG/1920]
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Thanks Emily,
We really appreciate your feedback and understand RD (esp. Team 25) is significantly understaffed. We look forward to Julia's status on where this action may be in her queue. It was my understanding, this action had been communicated as our top non-PRIA action under EPA Company No. 71995. When Dan Kenny returns to the office, James will loop in with him on our top priorities.

Kindest Regards, Ona

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Friday, July 12, 2019 3:16 PM
To: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>; Kerr, Julia <kerr.julia@epa.gov>

Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Ona,

This action is assigned to Julia Kerr (copied). As you know, we have a severe backlog of non-PRIA actions due to a variety of challenges we are facing as a program, especially low resources and understaffing. Unfortunately, something that was submitted in September of last year is not nearly as old as many actions that we have not been able to get to, so I doubt it is at the top of Julia's queue. She is out of the office on travel this week but will be back next week and can give you a better idea of where this action is in her queue.

I know management has worked with registrants to identify their priorities and as far as I know, this is not one that was singled out. If I'm wrong about that, please contact Dan Kenny so that he can pass that information onto us.

Best regards,
Emily

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Sent: Thursday, July 11, 2019 10:44 AM

To: Schmid, Emily <Schmid.Emily@epa.gov>

Cc: james.m.nyangulu@monsanto.com

Subject: FW: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Good Morning Emily,

Hope all is well with you. I understand Reuben has departed OPP for the Office of Water. I'm hoping you may be able to provide some feedback on the status of this pending **Master Label amendment EPA# 71995-25 submitted 9/11/2018**; which we have not received any response. This action has become quite urgent for us, as we would like to implement for the 2020 season revised labels for this residential concentrate product consistent with the recent acceptance of EPA# 71995-37 dated 3/28/2019. Much of the proposed label language and formatting of this action is the same as EPA# 71995-37.

We would greatly appreciate any feedback regarding the expected timing. I've included the submission information below and attached the cover memo for your reference.

Kindest Regards, Ona

Ona Maune

Lawn & Garden Regulatory Affairs Manager

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Bayer US
Monsanto Company
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Chesterfield, Missouri, 63017, USA
Office: +1 636.737.9577
E-mail: ona.maune@bayer.com
Web: <http://www.bayer.com>

From: Kenny, Daniel <Kenny.Dan@epa.gov>

Sent: Thursday, June 06, 2019 8:59 AM

To: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>

Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hello Ona. Reuben is still with the Herbicide Branch until sometime in July, so for the time being, you can still contact him.

Regards,
Dan Kenny

Daniel Kenny, Chief
Herbicide Branch
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Sent: Wednesday, June 05, 2019 3:53 PM

To: Kenny, Daniel <Kenny.Dan@epa.gov>

Cc: james.m.nyangulu@monsanto.com

Subject: FW: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Good Afternoon Dan,

We understand Reuben has departed RD and would like to follow-up on the status of this important pending Master Label amendment submitted 9/11/2018; which we had not received any feedback. We understand that the team is short staffed with a significant backlog of non-PRIA fast track amendments. However, we would like to implement revised labels for this residential concentrate product consistent with the recent acceptance of EPA# 71995-37 dated 3/28/2019. Much of the proposed label language and formatting of this action is the same as EPA# 71995-37.

Any feedback regarding the expected timing would be helpful to share with our business people. I've included the submission information below and attached the cover memo for your reference.

Please let me know if you have questions. As always, thanks in advance for your assistance.

Kindest Regards, Ona

Ona Maune
Lawn & Garden Regulatory Affairs Manager

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Bayer US
Monsanto Company
Crop Science Division
700 Chesterfield Parkway West FF4B
Chesterfield, Missouri, 63017, USA
Office: +1 636.737.9577
E-mail: ona.maune@bayer.com
Web: <http://www.bayer.com>

From: MAUNE, ONA [AG/1005]
Sent: Wednesday, May 29, 2019 4:36 PM
To: Baris, Reuben <Baris.Reuben@epa.gov>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: FW: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Good Afternoon Reuben,
I'm following up on my previous requests regarding the status in queue of this ML amendment and whether this action has been assigned to a reviewer on your team. I would really appreciate any estimated timing information that I could share with our business folks.

Kindest Regards, Ona

From: MAUNE, ONA [AG/1005]
Sent: Wednesday, May 01, 2019 11:45 AM
To: Baris, Reuben <Baris.Reuben@epa.gov>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: FW: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Reuben,
Hope all is well with you. I wanted to follow-up on my previous inquiry regarding the status of this ML amendment submitted 9/11/2018 (CDX_2018_006941). As mentioned below, this label is similar to the recently approved label amendment for EPA# 71995-37.

Thanks in advance. Kindest Regards, Ona

From: MAUNE, ONA [AG/1005]
Sent: Tuesday, April 09, 2019 2:22 PM
To: 'Baris, Reuben' <Baris.Reuben@epa.gov>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: FW: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Welcome Back Reuben,
I just wanted to reach out to confirm the status in queue and whether this ML amendment action has been assigned to a reviewer.

As noted below, this label amendment has similar language text and formatting to the recently approved label amendment for EPA# 71995-37. I've attached the cover memo for your reference.

Please let me know if you have any questions. Kindest Regards, Ona

From: Ondish, Mindy <ondish.mindy@epa.gov>
Sent: Tuesday, April 09, 2019 11:14 AM
To: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>; Baris, Reuben <Baris.Reuben@epa.gov>
Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Ona, forwarding to Reuben since this product is on his team.

Mindy Ondish

Product Manager 23 | Herbicide Branch | Registration Division
U.S. Environmental Protection Agency | Office of Pesticide Programs
(703)605-0723 | www.epa.gov/pesticide-registration

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Sent: Tuesday, April 09, 2019 11:16 AM

To: Ondish, Mindy <ondish.mindy@epa.gov>

Cc: james.m.nyangulu@monsanto.com

Subject: EPA# 71995-25 Roundup Weed & Grass Killer Super Concentrate ML Amendment: Submitted 9/11/2018 (CDX_2018_006941)

Hi Mindy,

I wanted to see if you could check the status and if a reviewer has been assigned to a pending Master Label amendment **EPA# 71995-25** submitted **9/11/2018 (CDX_2018_006941)**. We understand that the team is short staffed with a significant backlog of non-PRIA fast track amendments. However, we would like to implement revised labels for this residential concentrate product consistent with the recent acceptance of EPA# 71995-37 dated 3/28/2019. Much of the proposed label language and formatting of this action is the same as EPA# 71995-37.

Any feedback regarding the expected timing would be helpful to share with our business people. I've included the submission information below and attached the cover memo.

Please let me know if you have questions. As always, thanks in advance for your assistance.

Kindest Regards, Ona

Ona Maune

Lawn & Garden Regulatory Affairs Manager

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Chesterfield, Missouri, 63017, USA
Office: +1 636.737.9577
E-mail: ona.maune@bayer.com
Web: <http://www.bayer.com>

From: PRIARegistrationTracking@epa.gov <PRIARegistrationTracking@epa.gov>

Sent: Wednesday, September 12, 2018 10:33 AM

To: AFFAIRS, REGULATORY [AG/1000] <regulatory.affairs@monsanto.com>

Cc: Diapao.Banza@epa.gov; oppcommunications@epa.gov

Subject: 71995-25: PRIA TRACKING MILESTONE # 1

Email: regulatory.affairs@monsanto.com

Your application dated 09/10/2018 for a Amendment, ROUNDUP WEED & GRASS KILLER SUPER CONCENTRATE, 71995-25 has been received by EPA's Office of Pesticide Programs.

Receipt number assigned:	1024646
EPA receipt date:	09/11/2018

ED_006453A_00002860-00009

If this submission is not subject to PRIA, this will be your last automated notification related to this submission.

MILESTONE 1 IS COMPLETED

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